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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tomoyuki Nakamura

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08/07/2009

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

08/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,339	Applicant(s) NAKAMURA ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 29 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) 3-27, 29, 33, 34 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 2 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Request for Continuing Examination of July 13, 2009, in response to the Action of March 11, 2009 is acknowledged. It is acknowledged that Claims 1, 2, and 35 have been amended. Claims 1-27, 29, and 33-46 are pending. Claims 3-27, 29, 33, 34, and 36-46 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1, 2, and 35 are hereby reconsidered.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/lack of enablement, for the reasons explained in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants argue that Claim 1 is now directed towards a peptide which consists of an amino acid sequence having at least 90% identity to SEQ ID NO: 6, retaining a consensus Arg-Gly-Asp motif, and having binding activity for a human $\alpha v\beta 3$, $\alpha v\beta 5$, or $\alpha 9\beta 1$ integrin that binds to full-length human danc. The present specification and Nakamura et al, 2000 provide enablement for such a peptide and therefore this rejection is overcome.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that Claim 1 is so amended. However, neither the specification nor the prior art enable the skilled artisan to make and use any peptide having at least 90% identity to SEQ ID

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NO: 6 and having binding activity for a human $\alpha v\beta 3$, $\alpha v\beta 5$, or $\alpha 9\beta 1$ integrin that binds to full-length human dance. The family of integrins, including $\alpha v\beta 3$, $\alpha v\beta 5$, or $\alpha 9\beta 1$, are structurally and functionally diverse (van der Flier et al, 2001). The specification fails to teach binding of any peptide having at least 90% identity to SEQ ID NO: 6 to any human integrin. For these reasons and those explained in the prior action, the specification fails to enable the skilled artisan to make and use all such peptides without the undue burden of testing for binding to any human protein having any structure and the activity of any $\alpha v\beta 3$, $\alpha v\beta 5$, or $\alpha 9\beta 1$ integrin to bind full-length human dance.

Regarding Nakamura et al, 2000, said publication fails to teach binding of SEQ ID NO: 6, or any peptide having at least 90% identity thereto, to any human $\alpha v\beta 3$, $\alpha v\beta 5$, or $\alpha 9\beta 1$ integrin that binds full-length human dance.

For these reasons and those explained in the prior action, rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/lack of enablement, is maintained.

Examiner's note: The protein sequence in Nakamura et al, 2000 named "DANCE" (Fig 1A) does not comprise SEQ ID NO: 6 herein.

Written Description

Rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior actions, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the same arguments set forth above for the enablement rejection. These arguments are not found to be persuasive for the following reasons. The claims are directed to the genus of any peptide, having at least 90% identity to SEQ ID NO: 6, wherein the peptide binds to any human protein having any structure and the activity of any

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$\alpha\text{v}\beta 3$, $\alpha\text{v}\beta 5$, or $\alpha 9\beta 1$ integrin to bind full-length human dance. The specification fails to teach no peptides having said binding activity. Thus the specification fails to describe said genus of peptides in a manner such the skilled artisan would recognize Applicants were in possession of said genus. For these reasons and those explained in the prior action, rejection of Claims 1, 2, and 35 under 35 U.S.C. 112, first paragraph/written description, is maintained.

Claim 1, 2, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 introduces the limitation of “having an activity to bind to a human integrin selected from the group consisting of $\alpha\text{v}\beta 3$, $\alpha\text{v}\beta 5$, or $\alpha 9\beta 1$, which integrin is capable of binding to full length human DANCE polypeptide”. The specification fails to describe said limitation and, thus, Claim 1, and dependent Claims 2 and 35, are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

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It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652